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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,792	02/11/2004	Dale B. Schenk	15270J-004766US	304I
20350 7590 04/03/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER KOLKER, DANIEL E				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,792

Applicant(s)

SCHENK ET AL.

Examiner

DANIEL KOLKER

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 10/30/07.

DETAILED ACTION

1. The remarks and amendments filed 30 October 2007 have been entered. Claims 119 – 143 are pending and under examination.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2007 has been entered.

Inventorship

3. In view of the papers filed 30 October 2007, the inventorship in this nonprovisional application has been changed by the deletion of Frederique Bard and Theodore Yednock.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Withdrawn Rejections and Objections

4. The rejections under 35 USC 103(a) are withdrawn in light of the declaration filed 30 October 2007. The declaration filed on 30 October 2007 under 37 CFR 1.131 is sufficient to overcome the Chain (WO 01/42306) reference. The declaration provides evidence of reduction to practice of Aß 1–7 linked to a toxoid prior to the effective filing date of Chain. At paragraph 8 the declaration states that Aß 1–7 linked to a toxoid was conceived prior to 8 December 1999, and provides evidence of such conception in Exhibit D. The declaration also provides evidence of reduction to practice of this compound prior to 8 December 1999; see for example paragraph 10 of the declaration and Exhibit F. The compound described in the declaration is a species of the genus encompassed by claim 119. While it is not identical to that of instant claim 125, the differences between claim 125 and the compound disclosed in the declaration would have been obvious to one of ordinary skill in the art, particularly in view of Collier (U.S. 5,601,827, of record) and Van den Dobbelaar (Scand J. Immunol 1995, of record), which both discuss the use of CRM197 in immunizing compositions.

As the declaration provides evidence of possession of the claimed invention prior to the effective date of one of the references, it is sufficient to antedate the reference and overcome the rejections of record under 35 USC 103(a).

New Rejections and Objections
Specification

5. The amendments filed 2 June 2006 and 30 October 2007 are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: These amendments each amend paragraph [0126] to include the new limitation "CRM 197", which does not find support in the disclosure as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 125 – 127, 129 – 130, 138 – 140, and 142 – 143 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The examiner is unable to find support for the specific limitation CRM197 as the toxoid to which A β 1 – 7 is linked in the disclosure as originally filed. This limitation was first introduced in the amendment filed 2 June 2006. While applicant indicated, in the remarks filed 2 June 2006, that support for this limitation could be found at paragraph [0126] of the specification, that paragraph as originally filed did not include the specific limitation CRM 197. The paragraph spoke to diphtheria toxoids generally but not the specific CRM 197 toxoid. Thus claims which recite this limitation are drawn to new matter.

Priority

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 09/580018 and 09/723544, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The previously-filed applications do not provide support for claims 125 – 127, 129 – 130, 138 – 140, and 142-143, as the prior-filed applications fail to disclose the specific toxoid CRM 197, recited in these claims. Therefore, priority to the previously-filed applications for is denied these claims; the effective filing date is 11 February 2004, the date the instant application was filed.

Should applicant disagree with the examiner's factual determination, applicant should provide evidence or point to evidence currently of record which indicates that the previously-filed applications do in fact provide support for this limitation. This could be accomplished, for example, by pointing out the specific page and line numbers in the applications which describe CRM197 linked to A β 1-7.

For the purposes of applying prior art, the effective filing date of each pending claim is as follows:

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<u>Claim number</u>	<u>Effective filing date</u>
119 -124	5/26/2000
125-127	2/11/2004
128	5/26/2000
129-130	2/11/2004
131-137	5/26/2000
138-140	2/11/2004
141	5/26/2000
142-143	2/11/2004

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 125 – 127, 129 – 130, 138 – 140, and 142 – 143 are rejected under 35 U.S.C. 102(e) as being anticipated by Arumugham (U.S. Patent Application Publication 2007/0161088, published 12 July 2007, filed 17 December 2004, and claiming benefit of a provisional application filed 17 December 2003)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Note the reference claims the same patentable invention and cannot be overcome with a declaration under 37 CFR 1.131.

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Arumugham teaches and claims a composition comprising Ab 1-7 linked to CRM197. See for example Arumugham, claims 400, 403, 405, and 409. The reference teaches chemical cross-linking (see paragraph [0008]) as recited in instant claims 125 and 138, fusion peptides with both N- and C-terminal linkages as encompassed by claims 126 – 127, 129 – 130, 139 – 140, and 142 – 143. The reference also teaches QS-21 is an appropriate adjuvant (see for example claim 416). Thus Arumugham teaches the invention set forth in claims 125 – 127, 129 – 130, 138 – 140, and 142 – 143.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 119, 121 – 125, and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selkoe (U.S. Patent 5,262,332, issued 16 November 1993), Wong (1985. Proc. Natl. Acad. Sci. USA 82:8729-8732, reference 219 on IDS filed 6 February 2007) and Penney (U.S. Patent 5,773,007, issued 30 June 1998, filed 26 August 1994, claiming benefit of earlier-filed applications in 1993 and 1990).

Selkoe teaches methods of making antibodies to A β protein that are to be used for detection. Specifically, at column 2 lines 36 – 44 Selkoe teaches methods of diagnosing Alzheimer's disease by contacting samples from patients with antibodies that are capable of identifying β -AP (beta amyloid protein) or "a β -AP fragment of about 8 or more amino acids". At column 3 line 51 – column 4 line 24 Selkoe teaches that fragments of "about 8 or more amino acid residues" can be used to make antibodies to β -AP. Thus the reference is on point to products for making antibodies that bind to A β consisting of fragments of "about 8" amino acids of β -AP. As residues 1 – 7 of A β , recited in claim 119, is a fragment 7 residues long, and 7 is clearly "about 8" residues, the reference is on point to claim 119. Selkoe teaches that up to 250 μ g of protein can be administered for production of antibodies (column 17 lines 34 – 40), which is on point to claims 121 – 124. However Selkoe does not teach linking the fragment of the A β protein to a toxoid from a pathogenic bacterium as recited in claims 119 and 131.

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Wong teaches conjugates for production of antibodies against A β . Specifically, Wong teaches a conjugate (called OP1) comprising residues 1 – 10 of A β conjugated to keyhole limpet hemocyanin (p. 8729 second column third complete paragraph – p. 8730 first column), which is an antigen that can increase the immune system's reaction to the molecule to which it is conjugated. Wong teaches that the antibodies raised against this conjugate are useful for detection of A β and diagnosis of Alzheimer's disease. However Wong does not teach residues 1 – 7 of A β linked to a carrier which is a toxoid from a pathogenic bacterium as recited in claims 119 and 131.

Penney teaches that purified antigens are often not effective in eliciting an antibody response, and so to boost the response one should include an immunostimulant, such as the toxoid CRM 197, encompassed by claims 119 and 131 and recited in claim 125 (see column 1 line 63 – column 2 line 8). Penney teaches that any carrier molecule can be used, including Keyhole Limpet Hemocyanin and any of several toxoids from pathogenic bacteria, including but not limited to CRM (see column 5 first paragraph). Penney teaches covalent linkage, as encompassed by claim 125. Penney teaches that adjuvants can optionally be added to antibody-inducing compositions in order to mitigate any local hypersensitivity to the carrier (column 2 lines 7 – 15), which is on point to claim 131, part (b). However Penney does not teach conjugates comprising residues 1 – 7 of A β as encompassed by claims 119 and 131.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to make a composition comprising residues 1 – 7 of A β peptide linked to CRM 197, with a reasonable expectation of success. The motivation to do so would be to stimulate the host animal's immune system to make more antibodies, which could then be used in the diagnostic assays of either Selkoe or Wong. Selkoe teaches that "about 8" amino acids should be used in raising antibodies, and Wong points to the N-terminus of the A β protein as that region which is suitable for making antibodies to be used in diagnostic assays. Wong teaches that residues 1 – 10 of A β are to be coupled to a heterologous protein for the purpose of increasing antigenicity, so it would have been obvious to one of ordinary skill in the art to couple the shorter peptide (i.e., residues 1 – 7 of A β peptide) to a heterologous protein to increase antigenicity. Combining these teachings would have been obvious to one of ordinary skill in the art as both Selkoe and Wong teach making antibodies with these short peptides. Furthermore Penney teaches that CRM 197 can be substituted for KLH as a heterologous peptide used to increase antigenicity. Thus it would be reasonable to expect success.

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10. Claims 119 – 125 and 131 - 132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selkoe, Wong, and Penney as applied to claims 119, 121 – 125, and 131 above, and further in view of Restifo (U.S. Patent 5,733,548, of record).

The reasons why claims 119, 121 – 125, and 131 are obvious over Selkoe, Wong, and Penney are set forth above. However none of the references explicitly teaches a plurality of additional copies of the relevant antigen.

Restifo discloses that multiple copies of a peptide can be included in order to increase the immunogenicity of said peptide, and that this method should be effective even in those cases where a single copy of the peptide itself is not antigenic (see column 4 lines 32-36 and column 5 lines 15-22). Thus the reference is on point to claims 120 and 132. However Restifo does not teach comprising residues 1 – 7 of A β as encompassed by claims 119 and 131.

It would have been obvious to one of ordinary skill in the art to include multiple copies of the antigen, as suggested by Restifo, with a reasonable expectation of success. The motivation to do so would be to increase the immune response to the peptide antigen. The artisan of ordinary skill would realize that a small peptide (i.e. one "about 8" amino acids long as taught by Selkoe) would be unlikely to elicit a strong immune response on its own. Additionally, the fact that Wong used immune-boosting KLH in raising antibodies to a slightly larger peptide (residues 1 - 10 of A β) indicates to the artisan of ordinary skill the need to increase the immune response to the peptide. Thus the artisan would have been motivated to include multiple copies of the antigen.

11. Claims 119, 121 – 125, 131, and 133 – 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selkoe, Wong, and Penney as applied to claims 119, 121 – 125, and 131 above, and further in view of Hancock (U.S. Patent 5,723,130, issued 3 March 1998).

The reasons why claims 119, 121 – 125, and 131 are obvious over Selkoe, Wong, and Penney are set forth above. Note that Selkoe teaches the doses recited in claims 134 – 137 and chemical cross-linking as recited in claim 138. Penney teaches that adjuvants can be added to the compositions. However none of Selkoe, Wong, or Penney teaches the specific adjuvant QS-21 as recited in claim 133.

Hancock teaches QS-21 (recited in claim 133) is particularly suitable as an adjuvant as it increases the immune response, resulting in more antibodies that tightly bind to the antigen

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administered (see column 2 lines 25 – 35 for example). However Hancock does not teach comprising residues 1 – 7 of A β as encompassed by claims 119 and 131.

It would have been obvious to one of ordinary skill in the art to select QS-21 taught by Hancock as the adjuvant to be included in the compositions rendered obvious by Selkoe in view of Wong and Penney, with a reasonable expectation of success. The motivation to do so would be to select an adjuvant known to be particularly effective in eliciting antibodies, which could then be used in the methods taught by Selkoe and by Wong.

12. Claims 119, 121 – 131, and 133 – 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selkoe, Wong, Penney, and Hancock as applied to claims 119, 121 – 125, 131, and 133 – 138 above, and further in view of Collier (U.S. Patent 5,601,827).

The reasons why claims 119, 121 – 125, 131, and 133 – 138 would have been obvious to one of ordinary skill in the art are set forth above. However none of the references cited explicitly teaches fusion proteins comprising A β or fragments thereof as recited in claims 128 and 141, or the specific N- and C-terminal linkages recited in claims 126 - 127, 129 - 130, 139 - 140, and 142 - 143.

Collier teaches vectors for production of diphtheria toxoids, such as CRM-197 (see column 1 final paragraph) and teaches that the vectors can be used for construction of fusion proteins between a diphtheria toxoid and an antigen (see column 4 final paragraph and column 9 final paragraph). The reference is thus on point to fusion proteins, as recited in claims 128 and 141. Collier teaches that construction of vectors for fusion proteins is well-known in the art, but does not explicitly teach the specific N- and C-terminal linkages recited in claims 126 - 127, 129 - 130, 139 - 140, and 142 - 143.

It would have been obvious to one of ordinary skill in the art to use the vectors from Collier to make fusion proteins between A β 1-7 and CRM 197, as rendered obvious by Selkoe in view of Wong, Penney, and Hancock. Collier teaches that the fusion protein method is particularly useful to produce those proteins which will be administered for production of antibodies, so it would be reasonable to expect success in using such methodology. Additionally, as Collier teaches that fusion proteins are generally known in the art, and re-arrangement of parts is generally not considered a patentable contribution (see MPEP § 2144.04(VI)), selection of either the N- or C-terminus of the A β fragment would have been obvious. Selection of a particular element from among a finite number of possible solutions

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where the results are predictable can be considered obvious (see MPEP § 2143, section entitled "Exemplary Rationales" in discussing the Supreme Court's decision in *KSR International Co v. Teleflex Inc.*). Here, there are only 2 possible solutions (attachment at the N- or C-terminus), and Collier indicates that the fusion protein art was highly developed; note the patent was filed in 1995.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 119 – 143 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 398 – 416 of copending Application No. 10/583503. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims encompass A β 1-7 fragments coupled to CRM197; see for example claims 403, 406, 409, 412, 415, 419, and 422 of the '503 application.

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The claims in the '503 application would anticipate the instant claims. Note that while the applications share no inventors, there is a common assignee (Elan).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Inventorship

14. Claims 119 – 143 are directed to an invention not patentably distinct from claims 398 – 416 of commonly assigned application 10/583503. Specifically, in each case the claims encompass A β 1-7 fragments coupled to CRM197; see for example claims 403, 406, 409, 412, 415, 419, and 422 of the '503 application.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/583503, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./

Patent Examiner, Art Unit 1649

April 3, 2008

/Robert C. Hayes, Ph.D./

Primary Examiner, Art Unit 1649